

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-16 are pending in the application, with 1 and 11 being the independent claims. Claims 2-7, 9, 10, and 12-16 are original while Claims 1, 8, and 11 have been amended. Claims 17-22 are withdrawn from consideration because of a prior restriction/election requirement. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Claims 1-12 and 14-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,256,137 to Sage, Jr. (hereinafter “Sage”) and U.S. Patent No. 6,317,629 to Haak et. al. (hereinafter “Haak”) in view of U.S. Patent No. 4,340,047 to Tapper et. al. (hereinafter “Tapper”). Claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Sage or Haak, in view of Tapper and in further view of U.S. Pat. No. 5,983,134 to Ostrow (hereinafter “Ostrow”).

Based on the above amendment and the following Remarks, Applicant respectfully requests that the examiner reconsider all outstanding objections and rejections and they be withdrawn.

**I. Claims 1-12 and 14-16 are patentable over Sage and Haak in view of Tapper.**

Claims 1-12 and 14-16 stand rejected under 103(a) as being unpatentable over Sage or Haak in view of Tapper. For the following reasons, this rejection is respectfully traversed.

Claims 1 and 11 recite outputting an asymmetrical biphasic signal to treat neuropathy. The art cited by the examiner is directed to iontophoretic drug delivery. As such, these references

fail to disclose or suggest the claimed invention. Iontophoresis of the cited prior art is designed to transfer drugs through the skin, while the present invention stimulates nerve cells. The present invention delivers a unique wave form that duplicates a healthy nerve signal in order to wake up nerve cells, re-educate the nerve paths, and re-polarize the nerve cells.

The present invention uses a distinctive waveform—only perceived by a peripheral nerve—to duplicates a healthy peripheral nerve signal, and this signal can easily travel along a nerve path. Though normal biphasic waves are symmetrical, the present invention takes advantage of a biphasic wave with different shapes above and below the base line to awaken the nerve cells, re-educate the nerve paths, and restore the proper polarity to these cells, not deliver drugs transdermally as disclosed in the prior art.

As noted by examiner, Sage and Haak fail to teach an asymmetrical biphasic output signal. To cure this deficiency, the examiner points to Tapper. Tapper, however, does not disclose or suggest a asymmetric biphasic signal to treat neuropathy. Tapper's disclosure is directed to iontophoretic drug delivery and specifically notes that his invention does not refer to an asymmetric biphasic signal but rather two separate direct current pulses. See Tapper, Col. 2, ll. 60-66 ("a short reverse pulse 16 is not to be construed as referring to a conventional alternating current waveform....the waveform 12 represents a substantially direct current treatment interrupted at regular intervals of time by the reverse pulse"). The asymmetrical wave is important because the signal above the base line stimulates the nerve cell via a spike in voltage to resonate and trigger a nerve impulse larger than the input signal, similar to a transistor amplifying an electrical signal in a common electrical circuit. The signal below the line is different in shape because its purpose is to deliver more amperage (not voltage) in order to reset the polarity of the

nerve cell so that it can respond correctly to subsequent normal signals delivered by the patient himself. As the art cited fails to disclose or suggest all of the limitations of Claims 1 and 11, Claims 1-16 are allowable.

Claim 4 recites "...wherein the fluid is a water-electrolyte solution." Neither Sage nor Haak, taken alone or in view of Tapper disclose or suggest this limitation. As pointed to by the examiner, Haak discloses "the drug reservoir contains a neutral, ionized, or ionizable supply of the drug agent to be delivered." See Haak, Col. 6, ll. 9-15. Likewise, Sage discloses "a device having the drug reservoir." See Sage, Col. 3, ll. 18-19. Tapper discloses that "direct current is applied topically to the skin by a pair of electrodes." See Tapper, Col. 2, ll. 36-39. The art cited by the examiner is directed to iontophoretic treatment, rather than treating neuropathy; the drug reservoir feature of the various cited prior art is not necessarily a first and second container with a water-electrolyte solution. As the art cited fails to disclose or suggest this limitation, Claim 4 and all dependant claims are allowable.

Claim 10 recites "voltage...is adjusted based on the resistance between the first electrode and the second electrode." Neither Sage nor Haak, taken alone or in view of Tapper disclose or suggest this limitation. As pointed to by the examiner, Tapper discloses that "[a] variable resistor is used to control the amount of current which is permitted to flow." See Tapper, Col. 4, ll. 8-14. Tapper does not disclose, however, that the voltage is adjusted by the variable resistor based on the resistance between the first electrode and the second electrode.

Claim 11 now recites "a method for treating neuropathy." Sage and Tapper are directed to iontophoretic therapy. None of the references cited by the examiner disclose or suggest the

treatment of neuropathy with an asymmetrical biphasic signal. Because the cited references fail to teach every limitation and feature of the present invention, these claims are allowable.

**II. Claim 15 is patentable over Sage or Haak in view of Tapper and in further view of Ostrow.**

Neither Sage nor Haak taken alone or in combination disclose or suggest propagating the asymmetrical biphasic signal through a first extremity and a second extremity. To cure this deficiency the examiner turns to Ostrow. Ostrow, however, fails to disclose or suggest propagating an asymmetrical biphasic signal through a first extremity and a second extremity. Ostrow's invention is for is an apparatus with a flexible cuff. Though this single cuff may be capable of being attached to multiple body parts, during operation it may be attached only to a single extremity. See Ostrow, Col. 6, ll. 65-67 (“[t]he apparatus is comprised of a flexible cuff 12 for wrapping around a body part or limb”). As such, Sage and Haak in view of Ostrow, taken alone or in combination, fail to disclose or suggest the invention in Claim 15. The present invention can be connected to two extremities to affect the maximum amount of nerve tissue and treat peripheral neuropathy.

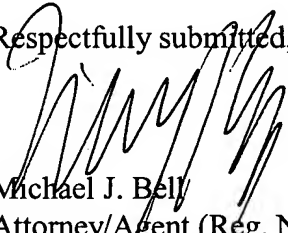
Because the references cited the examiner fail to disclose or suggest the claimed invention, Claims 1-16 are allowable. Therefore, applicant respectfully requests that the examiner withdraw the rejections of the claims.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,



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